REMARKS/ARGUMENTS

Claims 82-105 are pending. Claims 1-81 are canceled. No new matter has been added.

Applicants have submitted an Information Disclosure Statement identifying U.S. Patent No. 6,531,509 to Singer (the Singer patent). The Singer patent is directed to pharmaceutical formulations containing allegedly stable *aqueous* gabapentin granulations having a chloride ion concentration greater than 20 ppm, based on the weight of gabapentin. The specification defines "stable" as a gabapentin composition that initially contains less than 0.5% of a corresponding lactam and the conversion of gabapentin to its corresponding lactam does not exceed 0.2% by weight of gabapentin after one year of storage at 25°C and 60% atmospheric humidity.

In contrast to the Singer patent, Applicants claims 82-95 recite stable gabapentin formulations comprising a *non-aqueous* granulation of gabapentin. As described below, Applicant's formulations exhibit superior stability properties compared to the formulations of the Singer patent. Gabapentin formulations prepared with water as described in the Singer patent are less stable compared to Applicant's formulation because, when contacted with water, gabapentin is readily hydrolyzed to its corresponding lactam.

A comparison of Applicant's example 5, an alcoholic granulation, and example 8, an aqueous granulation, shows that aqueous granulations of gabapentin having more than 20 ppm of chloride ions exceed 0.2% lactam at 40°C and 75% relative humidity *prior to testing at 30 days*. However, the alcoholic granulation of example 5 did not exceed 0.2% lactam under the same conditions until after *more than 60 days*.

Claims Rejections - 35 U.S.C. §102(b) & §102(e)

In the Office Action, claims 1-4, 6-20, 53-58, 60-66, and 68-77 have been rejected under 35 U.S.C. §102(e) as allegedly being unpatentable over U.S. Patent No. 6,294,198 to Vilkov. Claims 65, 66, and 68-72, and 74-81 have been rejected under 35 U.S.C. §102(b) as allegedly being unpatentable over U.S. Patent No. 5,084,479 to Woodruff. These rejections are respectfully traversed as the Vilkov and Woodruff patents do not teach every element of the claims as amended.

The Vilkov and Woodruff patents do not teach stable non-aqueous granulations of gabapentin having at least 20 ppm of chloride ions. Indeed, the Vilkov patent does not teach a source of "anions of a mineral acid," e.g. chloride ions. The compositions of gabapentin tablets described in the examples and shown in tables 1, 2, and 3 do not include anions of a mineral acid at any concentration. The Office Action asserts that calcium stearate is a source of "anion of a mineral acid," but calcium stearate does not form a mineral acid, such as for example hydrochloric acid.

Moreover, the Woodruff patent does not teach stable non-aqueous granulations of gabapentin having at least 20 ppm of anions of a mineral acid. The Woodruff patent does not teach a source of "anions of a mineral acid," e.g. chloride ions. The Woodruff patent is limited to methods of using gabapentin compositions.

Accordingly, since the Vilkov & Woodruff patents do not teach all of the elements of Applicant's claims, withdrawal of the rejections under 35 U.S.C. §102(b) and §102(e) is requested.

Claims Rejections - 35 U.S.C. §103(a)

In the Office Action, claims 1-4, 6-24, 26-44, and 53-58 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Vilkov patent. This rejection is respectfully traversed because the cited art does not teach or suggest the claimed invention.

There is simply no suggestion for one of ordinary skill in the art to modify the Vilkov patent to achieve stable non-aqueous granulations of gabapentin having at least 20 ppm of chloride ions. Without such a suggestion, the present claims cannot be found obvious over the Vilkov patent.

The Prior art clearly teaches away from any suggestion to increase anion concentration above 20 ppm. U.S. Patent No. 6,054,482 to Augart (The Augart patent) was granted for identifying techniques that stabilize gabapentin formulations. The Augart patent teaches that chloride ion concentration should be *lower than 20 ppm* to avoid instability common in conventional compositions. The Vilkov patent simply does not teach or suggest the art skilled how to prepare stable non-aqueous granulations of gabapentin having greater than 20 ppm of chloride ions.

The Office Action points to no legally sufficient motivation for its proposed modification of the Vilkov patent. Indeed, the prior art suggests that a person of ordinary skill in the art would *not* assume that using a gabapentin salt in the process taught by the Vilkov patent would yield stable non-aqueous granulations of gabapentin having greater than 20 ppm of an anion. In fact, the prior art suggests the opposite.

Therefore, the cited references do not teach or suggest all the limitations of claims 82-105. Accordingly, withdrawal of the rejection under 35 U.S.C. §103(a) is requested.

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CONCLUSION

Applicant believes that the foregoing is a full and complete response to the Office Action of record. Accordingly, an early and favorable reconsideration of the rejections and allowance of all of pending claims 82-105 are respectfully requested.

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